Exhibit A

Declaration of Gillian Feiner

Under 28 U.S.C. § 1746, I, Gillian Feiner, declare under the penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. This declaration is submitted in support of the Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents or for in Camera Review.

2. I am an attorney in good standing admitted to practice in the Commonwealth of Massachusetts and I am Senior Enforcement Counsel in the office of Massachusetts Attorney General Maura Healey. I am admitted in these cases *pro hac vice*. *See* ECF 121. I make this Declaration based on my own personal knowledge and belief, and upon documents and information available to me as counsel to the Commonwealth of Massachusetts.

3. Exhibits B-T, filed together with this Declaration, each bearing prefix MCK-MAAG, were produced to the Massachusetts Attorney General by McKinsey & Company pursuant to Massachusetts General Laws chapter 93A § 6(6), and they are filed pursuant to that section, which provides that "such material or information may be disclosed by the attorney general in court pleadings or other papers filed in court."

Respectfully submitted this 18th day of November, 2020:

/s/ Gillian Feiner
Gillian Feiner, Mass. BBO No. 664152
Senior Enforcement Counsel
Office of the Attorney General
One Ashburton Place
Boston, MA 02108
617-963-2571
gillian.feiner@mass.gov

Exhibit B

Message

From: Rob Rosiello [CN=Rob Rosiello/OU=STA/OU=NorthAmerica/O=MCKINSEY]
Sent: 10/4/2008 3:12:31 PM
To: Maria Gordian [CN=Maria Gordian/OU=NYO/OU=NorthAmerica/O=MCKINSEY]
Subject: Fw: OTR Action Letters...
Attachments: NDA 22272 Action Letter.pdf; OxyContin S-058 IR letter.pdf

From: "Mallin, William" [William.Mallin@pharma.com]
Sent: 10/04/2008 10:41 AM AST
To: Rob Rosiello
Subject: Fw: OTR Action Letters...

Fyi

From: Weingarten, Brianne
To: Connelly, Beth; Fox, John; Green, Jerry; Kelly, Charles; Kelly, James; Kreppel, Rachel; Mallory, Charles; Perrino, Peter; Pollock, David; Sparta, Gregory; Udell, Andrew
Cc: Mallin, William; Gasdia, Russell; Udell, Howard; Kaiko, Dr Robert; Steiner, LaDonna; Fletcher, Mark; Mahony, Edward; Dolan, James; Innaurato, Mike; Strassburger, Philip; Santopolo, Anthony; Landau, Dr. Craig; Harris, Stephen; Schady, Kathleen; Zerillo, Jeffrey; Lundie, David
Sent: Sat Oct 04 09:12:34 2008
Subject: FW: OTR Action Letters...

All,

Please see the attached from FDA.

OTR Team, we will meet on Monday to study further.

BW

From: Santopolo, Anthony
Sent: Saturday, October 04, 2008 8:51 AM
To: Weingarten, Brianne
Cc: Santopolo, Anthony
Subject: Fw: Finally.....

This came last night. I sent to John and Craig.
Tony

Sent from my BlackBerry Wireless Handheld

From: Basham, Lisa
To: Santopolo, Anthony
Sent: Fri Oct 03 17:18:30 2008
Subject: Finally.....

<<NDA 22272 Action Letter.pdf>> <<OxyContin S-058 IR letter.pdf>>

The reason for two letters will become apparent as you review the content of each.

Warm Regards,

Lisa Basham, MS
Regulatory Project Manager
Division of Anesthesia, Analgesia and Rheumatology Products
301-796-1175


NDA 22272 Action Letter.pdf


OxyContin S-058 IR letter.pdf

New email: lisa.basham@fda.hhs.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-272

COMPLETE RESPONSE

Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-3431

Attention: Anthony C. Santopolo M.D.
Vice President, Regulatory Affairs

Dear Dr. Santopolo:

Please refer to your new drug application (NDA) dated November 29, 2007, received November 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OxyContin (Oxycodone Hydrochloride Controlled-Release Tablets), 10, 15, 20, 30, and 40 mg.

We acknowledge receipt of your amendments dated November 30, December 19, 20, and 21, 2007, and January 14, February 8, 12, 14 (2), and 15 (2), March 7, 10, 14, 18, 25 (2), and 27, April 11 and 23, May 7, and August 20, and September 26, 2008.

We also acknowledge receipt of your amendment dated April 23, 2008, which was not reviewed for this action. You may incorporate applicable sections of the amendment by specific reference as part of your response to the deficiencies cited in this letter.

We have completed the review of your application, as amended, and have determined that we cannot approve this application in its present form. We have described below our reasons for this action and, where possible, our recommendations to address these issues.

1. Provide a new product name for the reformulated strengths if you intend to continue to market the original formulation at any strength at the same time as you intend to market the reformulated tablets. It is not acceptable to have some reformulated strength tablets and the same original formulation strength tablets available on the market at the same time with the same product name.

2. Provide studies of the new formulation that demonstrate the effects of physical and/or chemical manipulation and that incorporate the following:

a. The testing must be conducted in a blinded manner, preferably by an independent third party.

b. The methods used to assess the physical characteristics of the product must be reassessed. Consult individuals experienced in the intentional extraction of oxycodone from OxyContin for abuse to determine the methods for testing that will most likely replicate the methods encountered once the product is marketed. The resultant testing methods should then undergo a validation procedure to ensure they are conducted in a reproducible and meaningful manner.

c. Consult experts on extraction techniques to fully assess your proposed extraction testing protocols and to evaluate the data upon completion.

d. Provide data documenting the amount of oxycodone released if the reformulated tablet is chewed after crushing or prior softening in water or in other solvents.

e. Conduct studies to determine the relative rate of release of the active pharmaceutical ingredient from all strengths of crushed and milled tablets to determine whether all dosage strengths retain the controlled-release properties after crushing and milling and that dose dumping does not occur. It is recommended that you extend the grinding time, for these studies as well as the extraction studies, to greater than one minute in order to obtain a more homogenous particle size powder.

f. Provide data documenting how altering the grinding conditions, such as longer grinding periods or the use of grinders other than regular coffee grinders, might affect the final particle size distribution of the tablets for all strengths and whether these efforts might render a product suitable for insufflation.

3. As noted during Division of Scientific Investigations inspection of Study OTR1005, accuracy of Period 1 oxycodone concentrations for subjects 5040-5042 in run 07307cga14a and subjects 5043, 5044, and 5046 in run 07307cgb14a cannot be assured. Therefore, before data from Study OTR1005 can be accepted, reanalyze and submit the data from study OTR1005 demonstrating bioequivalence after completely excluding data from subjects 5040, 5041, 5042, 5043, 5044, and 5045. Alternatively, reanalyze the plasma concentrations as identified and confirm the original values.

4. For the reasons described below, you must submit a proposed Risk Evaluation and Mitigation Strategy (REMS).

5. We reserve comment on the proposed labeling until the application is otherwise adequate. If you revise labeling, your response must include updated content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html.

SAFETY UPDATE

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(*b*). The safety update should include data from all nonclinical and clinical studies/trials of the drug under consideration regardless of indication, dosage form, or dose level.

1. Describe in detail any significant changes or findings in the safety profile.

2. When assembling the sections describing discontinuations due to adverse events, serious adverse events, and common adverse events, incorporate new safety data as follows:

   - Present new safety data from the studies for the proposed indication using the same format as the original NDA submission.
   - Present tabulations of the new safety data combined with the original NDA data.
   - Include tables that compare frequencies of adverse events in the original NDA with the retabulated frequencies described in the bullet above.
   - For indications other than the proposed indication, provide separate tables for the frequencies of adverse events occurring in clinical trials.

3. Present a retabulation of the reasons for premature study discontinuation by incorporating the drop-outs from the newly completed studies. Describe any new trends or patterns identified.

4. Provide case report forms and narrative summaries for each patient who died during a clinical study or who did not complete a study because of an adverse event. In addition, provide narrative summaries for serious adverse events.

5. Describe any information that suggests a substantial change in the incidence of common, but less serious, adverse events between the new data and the original NDA data.

6. Provide updated exposure information for the clinical studies/trials (e.g., number of subjects, person time).

7. Provide a summary of worldwide experience on the safety of this drug. Include an updated estimate of use for drug marketed in other countries.

8. Provide English translations of current approved foreign labeling not previously submitted.

RISK EVALUATION AND MITIGATION STRATEGIES (REMS) REQUIREMENTS

Title IX, Subtitle A, Section 901 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amends the FDCA to authorize FDA to require the submission of a REMS if FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks (section 505-1(a)). This provision took effect on March 25, 2008.

In accordance with section 505-1 of the FDCA, we have determined that a REMS is necessary for OxyContin (Oxycodone Hydrochloride Controlled-Release Tablets) to ensure that the benefits of the drug outweigh the risks of: 1) use in non-opioid-tolerant individuals; 2) abuse; and 3) overdose, both accidental and intentional. We have determined that under section 505-1, the REMS for this product must include a Medication Guide, elements to assure safe use, an implementation system, and must include a timetable for assessments. You must submit a proposed REMS and REMS Supporting Document prior to final approval of this new drug application. You have been directed to prepare a REMS for the previously approved formulation of OxyContin NDA 20-553. You should review the elements of that REMS in preparing this proposed REMS for NDA 22-272.

Use the following designator to prominently label all submissions relating to this REMS:

NDA 22-272 PROPOSED REMS

ADDITIONAL COMMENTS

1. Serious consideration should be given to using a new trade name for the reformulated product, even if you do not intend to have the reformulated product available on the market at the same time as the current formulation. This would serve several purposes. First, it would give the context of a new product to support the new education program. Second, direct comparison as a "new and improved" OxyContin with the potential for a false sense of security would be avoided. Third, a novel name would permit national abuse monitoring and prescription databases to be able to track use and misuse of the new formulation immediately upon marketing and would avoid the situation of a transitional period with overlap of the two formulations during which time there could be no meaningful tracking of either product.

2. We strongly recommend that you submit all promotional material for review by the Agency prior to dissemination of the material. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

   Food and Drug Administration
   Center for Drug Evaluation and Research
   Division of Drug Marketing, Advertising, and Communications
   5901-B Ammendale Road
   Beltsville, MD 20705-1266

OTHER

Within one year after the date of this letter, you are required to resubmit or take one of the other actions available under 21 CFR 314.110. If you do not take one of these actions, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. A resubmission

must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA Guidance for Industry *Formal Meetings With Sponsors and Applicants for PDUFA Products*, February, 2000 (http://www.fda.gov/cder/guidance/2125fnl.htm).

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Lisa Basham, Regulatory Project Manager, at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport
10/3/2008 05:06:03 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-553/S-058

INFORMATION REQUEST LETTER

Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-3431

Attention: Beth Connelly
Assistant Director, U.S. Regulatory Affairs

Dear Ms. Connelly:

Please refer to your supplemental new drug application dated May 21, 2007, received May 22, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OxyContin (Oxycodone Hydrochloride Extended-Release) Tablets.

We also refer to your submission dated February 14, 2008.

This supplemental new drug application proposes a risk management plan for OxyContin. We have completed the review of your application, as amended, and have determined that we cannot approve this application in its present form. It will be necessary for you to submit a proposed Risk Evaluation and Mitigation Strategy (REMS) for the reasons described below in place of the risk management plan.

For administrative purposes, please withdraw your supplemental new drug application S-058 and submit a new supplement containing the proposed REMS.

RISK EVALUATION AND MITIGATION STRATEGIES (REMS) REQUIREMENTS

Title IX, Subtitle A, Section 901 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amends the FDCA to authorize FDA to require the submission of a REMS for an approved drug if FDA becomes aware of new safety information and determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks (section 505-1(a)). This provision took effect on March 25, 2008.

Since OxyContin was approved on December 12, 1995, for the management of moderate to severe pain in patients where use of an opioid analgesic is indicated for more than a few days, we have become aware of postmarketing reports of overdose, abuse, and addiction associated with OxyContin. This information was not available when OxyContin was granted marketing

authorization. Therefore, we consider this information to be "new safety information" as defined in FDAAA.

Based on this new safety information, and in accordance with section 505-1 of the FDCA, we have determined that a REMS is necessary for OxyContin to ensure that the benefits of the drug outweigh the risks of: 1) use of dosages 60 mg and above in non-opioid-tolerant individuals; 2) abuse; and 3) overdose, both accidental and intentional.

Your proposed REMS must contain the following:

Medication Guide: As one element of a REMS, FDA may require the development of a Medication Guide as provided for under 21 CFR Part 208. Under 21 CFR Part 208 and in accordance with 505-1, you are responsible for ensuring that the Medication Guide is available for distribution to patients who are dispensed OxyContin. Pursuant to 21 CFR Part 208, FDA has determined that OxyContin poses a serious and significant public health concern requiring the distribution of a Medication Guide. The Medication Guide is necessary for patients' safe and effective use of OxyContin. FDA has determined that OxyContin is a product that has serious risks (relative to benefits) of which patients should be made aware because information concerning the risks could affect patients' decision to use, or continue to use OxyContin. FDA has also determined that OxyContin is a product for which patient labeling could help prevent serious adverse events.

Elements to Assure Safe Use: We have determined that elements to assure safe use are necessary to mitigate serious risks listed in the labeling of the drug. In addition, we have determined that the Medication Guide discussed above is not sufficient to mitigate the serious risks. Your REMS must include tools to manage these risks, including at least the following:

1) A plan to ensure that Oxycontin will only be prescribed by prescribers who are specially certified under 505-1(f)(3)(A) through the certification process described below. At a minimum the plan shall require that:
   (a) Prescribers are trained about:
      (i) proper patient selection
      (ii) appropriate product dosing and administration,
      (iii) general opioid use including information about opioid abuse and how to identify patients who are at risk for addiction
      (iv) the risks of OxyContin including:
         1. the risk of overdose caused by exposure to an essentially immediate release form of oxycodone due to crushing, chewing or dissolving OxyContin
         2. The risk of addiction from exposure to OxyContin
      (v) how to enroll patients into the REMS program
   (b) Prescribers have obtained certification by attesting to the following:
      (i) I have been trained and understand the risks and benefits of chronic opioid therapy

(ii) I understand OxyContin can be abused and this should be considered when prescribing or dispensing OxyContin in situations where I am concerned about an increased risk of misuse, abuse, or overdose, whether accidental or intentional.
(iii) I understand that OxyContin Tablets are indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.
(iv) I understand that OxyContin dosages of 60 mg and above are for use in opioid-tolerant patients only. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.
(v) I will prescribe OxyContin after ensuring documentation of safe use conditions described below.
(vi) I will enroll patients into the REMS program.

(c) The sponsor will maintain a list of the prescribers who have obtained the certification, and provide the list to those needing to verify that a prescriber has obtained the required certification.
(d) Prescribers will be retrained and recertified periodically, at a specified interval.

2) A plan to ensure that OxyContin is only dispensed by pharmacies, practitioners, or healthcare settings (e.g., hospitals) who are specially certified under 505-1(f)(3)(B) by requiring that:
(a) OxyContin is dispensed through certified pharmacies, practitioners, or healthcare settings. To obtain certification, a pharmacy, practitioner, or healthcare setting must agree to:
(i) Train their staff, including pharmacists and practitioners, about the REMS procedures and education materials
(ii) Dispense OxyContin after ensuring documentation of safe use conditions described below
(b) The sponsor will maintain a list of the pharmacies, practitioners, or healthcare settings who have obtained the certification, and provide the list to those needing to verify that the required certification has been obtained.
(c) Pharmacies, practitioners, or healthcare settings will be retrained and recertified periodically, at a specified interval.

3) A plan to ensure the drug is dispensed to patients with documentation of the following safe use conditions under 505-1(f)(3)(D):
(a) A prescriber must document that he or she:
(i) Has enrolled each patient by obtaining at the time of first prescribing and on a specified periodic frequency thereafter a signed physician-patient agreement form that documents safe use conditions, i.e., patients being prescribed the higher doses (i.e., 60 mg and above) are opioid tolerant; patients require chronic opioid around-the-clock analgesia for moderate to severe pain; patients have been counseled about the risks and benefits and appropriate use of OxyContin, and about the risk of overdose due to giving OxyContin to

someone for whom it has not been prescribed; patients have been provided and reviewed the Medication Guide; and patients have been instructed that OxyContin tablets are to be swallowed whole and are not to be broken, chewed, or crushed because taking broken, chewed, or crushed OxyContin tablets leads to rapid release and absorption of a potentially fatal dose of oxycodone.

(ii) Will provide a copy of the signed physician-patient agreement form to the sponsor.

(b) The sponsor will maintain a list of the patients who have been enrolled and verify patient enrollment to those needing to verify that a patient has been or has not yet been enrolled. The sponsor will provide a unique patient identifier when each patient is enrolled. Patient will always be tracked using this unique identifier so that the sponsor can monitor OxyContin prescribing for each patient.

(c) Pharmacies, practitioners, or healthcare settings who dispense OxyContin must document that the drug has been dispensed under the following safe use conditions:

(i) The pharmacy, practitioner, or healthcare setting has dispensed OxyContin only to enrolled patients, based on a valid prescription from a certified prescriber (enrolled patients and certified prescribers to be determined from a list maintained by the sponsor).

(ii) The pharmacy, practitioner, or healthcare setting has ensured that patients who are receiving the higher strengths (i.e., 60 mg and above) are opioid-tolerant.

(iii) The pharmacy, practitioner, or healthcare setting has counseled patients on appropriate product use.

(iv) The pharmacy, practitioner, or healthcare setting has provided each patient a Medication Guide with each prescription and instructed the patient to read it.

Implementation System: The REMS must include an implementation system to monitor and evaluate the implementation of the elements to assure safe use (outlined above) that require that the drug be dispensed to patients with documentation of safe-use conditions. Include an intervention plan to address any findings of non-compliance with elements to assure safe use and to address any findings that suggest an increase in risk.

The Implementation System must include:

- A database of all enrolled entities including prescribers, pharmacies, practitioners, healthcare settings, and patients.
- A plan to monitor distribution data and prescription data to ensure that only certified pharmacies, practitioners, and healthcare settings are distributing and dispensing OxyContin and that only certified prescribers are prescribing OxyContin
- A plan to monitor and conduct audits of certified pharmacies, practitioners, and healthcare settings to ensure these entities are only dispensing OxyContin after documenting safe use conditions.

Timetable for Assessment: The proposed REMS should include a timetable for assessment that shall be no less frequent than every six months for the first two years, and

annually thereafter once the REMS is initially approved. We recommend that you specify the interval that each assessment will cover and the planned date of submission to the FDA of the assessment. We recommend that assessments be submitted within 60 days of the close of the assessment interval.

Each assessment must assess the extent to which the elements to assure safe use of your REMS are meeting the goals of your REMS and whether the goals or elements should be modified.

In accordance with section 505-1, within 60 days of the date of this letter, you must submit a proposed REMS and a REMS supporting document. The REMS, once approved, will create enforceable obligations.

We suggest that your proposed REMS submission include two parts: a "Proposed REMS" and a "REMS Supporting Document." Attached is a template for the Proposed REMS that you should complete with concise, specific information (see Appendix A). Include information in the template that is specific to your proposed REMS for OxyContin. Additionally, all relevant proposed REMS materials including enrollment forms, informed consents, and educational and communication materials should be appended to the proposed REMS. Once FDA finds the content acceptable, we will include this document as an attachment to the approval letter that includes the REMS. The REMS, once approved, will create enforceable obligations.

The REMS Supporting Document should provide a thorough explanation of the rationale for and supporting information about the content of the proposed REMS and should include the following sections as well as a table of contents:

1. Background
2. Goals
3. Supporting Information on Proposed REMS Elements
   a. Medication Guide and/or Package Insert
   b. Communication Plan
   c. Elements to Assure Safe Use
   d. Implementation System
   e. Timetable for Assessment of the REMS
4. Information Needed for Assessments
5. Other Relevant Information

Information needed for assessment of the REMS may include but may not be limited to:

1. A survey of patients' or healthcare providers' understanding of the serious risks of OxyContin
2. A report on the status of the training and certification program for healthcare professionals
3. A report on the status of patient enrollment.
4. An evaluation of the effectiveness of the REMS program through:

- a claims study to evaluate OxyContin utilization patterns including opioid-tolerant utilization patterns before and after implementation of your REMS
- an analysis and summary of surveillance and monitoring activities for abuse, misuse and overdose, and any intervention taken resulting from signals of abuse, misuse and overdose

5. A report on periodic assessments of the distribution and dispensing of the Medication Guide in accordance with 21 CFR 208.24
6. A report on failures to adhere to distribution and dispensing requirements, and corrective actions taken to address noncompliance

Prominently identify the amendment containing the proposed REMS with the following wording in bold capital letters at the top of the first page of the submission:

NEW SUPPLEMENT FOR NDA 20-553 [assigned #] PROPOSED REMS

Prominently identify subsequent submissions related to the proposed REMS with the following wording in bold capital letters at the top of the first page of the submission:

SUPPLEMENT[assigned #]
PROPOSED REMS – AMENDMENT

If you have any questions, call Lisa Basham, Regulatory Project Manager, at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, MD
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Attachment

Attachment A

Application number TRADE NAME (DRUG NAME)

Class of Product as per label

Applicant name
Address
Contact Information

PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(S):

List the goals and objectives of the REMS.

II. REMS ELEMENTS:

A. Medication Guide or PPI

A Medication Guide will be dispensed with each [drug name] prescription. [Describe in detail how you will comply with 21 CFR 208.24.]

B. Communication Plan

[Applicant] will implement a communication plan to healthcare providers to support implementation of this REMS.

List elements of communication plan. Append the printed material and web shots to the REMS Document

C. Elements To Assure Safe Use

List elements to assure safe use included in this REMS. Elements to assure safe use may, to mitigate a specific serious risk listed in the labeling, require that:

A. Healthcare providers who prescribe [drug name] have particular training or experience, or are specially certified. Append any enrollment forms and relevant attestations/certifications to the REMS;

B. Pharmacies, practitioners, or healthcare settings that dispense [drug name] are specially certified. Append any enrollment forms and relevant attestations/certifications to the REMS ;

C. [Drug name] may be dispensed to patients only in certain healthcare settings (e.g., hospitals);

D. [Drug name] may be dispensed to patients with documentation of safe-use conditions;

E. Each patient using [drug name] is subject to certain monitoring. Append specified procedures to the REMS; or

F. Each patient using [drug name] be enrolled in a registry. Append any enrollment forms and other related materials to the REMS Document.

D. Implementation System

Describe the implementation system to monitor and evaluate implementation for, and work to improve implementation of, Elements to Assure Safe Use (B),(C), and (D), listed above .

E. Timetable for Submission of Assessments

Specify the timetable for submission of assessments of the REMS. The timetable for submission of assessments at a minimum must include an assessment by 18 months, 3 years, and in the 7th year after the REMS is initially approved, with dates for additional assessments if more frequent assessments are necessary to ensure that the benefits of the drug continue to outweigh the risks.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport
10/3/2008 05:03:52 PM

Exhibit C

Message

From: Maria Gordian [CN=Maria Gordian/OU=NYO/OU=NorthAmerica/O=MCKINSEY]
Sent: 10/24/2008 1:03:38 PM
To: Rob Rosiello [CN=Rob Rosiello/OU=STA/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]; Martin Elling [CN=Martin Elling/OU=NJE/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]
Subject: Re: Prudue

Agree

Sent from my BlackBerry Wireless Handheld

----- Original Message -----
From: Rob Rosiello
Sent: 10/24/2008 06:27 AM EDT
To: Martin Elling; Maria Gordian
Subject: Re: Prudue
agree below...do have to get in loop with board...can tell things moving south for john....will call him this morning...

----- Original Message -----
From: Martin Elling
Sent: 10/24/2008 06:18 AM EDT
To: Maria Gordian; Rob Rosiello
Subject: Re: Prudue
Maria-
Thanks for update. Sounds like great progress in troubled times. We should engage John/Craig quickly on the broader entity strategy question. Not withstanding the setbacks, given where the market is these days, they should assess what their options are from go-it-alone, to Genentech of pain, to JV, to sale.
Rob, how do we best move this forward in your mind?
M

Sent from my BlackBerry Wireless Handheld

----- Original Message -----
From: Maria Gordian
Sent: 10/23/2008 11:17 PM EDT
To: Rob Rosiello; Martin Elling
Subject: Re: Prudue
REMS work...

1) very good progress...on track to deliver first draft of strategy to Board for next week

2) expanding team to do market analysis of feasibility of REMs response and commercial implication. We had intended to do this...but Dr Richard , called commercial guys looking for this info.

OTR..

1) focus on the family is now on the response to the non approval letter for OTR.

2) we Craig up for 2 hour working session with our FDA expert...it was extremely helpful to get insights on how they are crafting the response. I have also given my input on the document.

3) Intention is to send this document Monday

Broader Strategy work

1) Two board members approached craig (John Sackler and Peter B)...basically "blessed" him to do whatever he thinks is necessary to "save the business" The focus is on OTR and Oxycontin...but have been helping Craig understand broader context and the value to thinking through the braider portfolio. I believe there is a good opportunity to get

another project here.

John,

I) I only had a chance to touch with John briefly. he is aware of the critical role we are playing in pulling REMs together and is very appreciative.

2) did not get a chance to get into deeper dialogue around strategy. Still think John head is not focus on these questions...he more narrowly focus on REM response and OTR response.

Maria Gordian
Principal
McKinsey and Company
55 East 52 Street
New York, NY 10055
(212) 446-8619 - Office Phone
(212) 446-8621 - Office Fax
(917) 495-2432 - Mobile
E-mail: maria_gordian@mckinsey.com

Assistant: Michelle Lopez, 212-446-7274

Exhibit D

Message

From: Rob Rosiello [CN=Rob Rosiello/OU=STA/OU=NorthAmerica/O=MCKINSEY]
Sent: 1/20/2009 11:30:38 AM
To: Maria Gordian [CN=Maria Gordian/OU=NYO/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]; Martin Elling [CN=Martin Elling/OU=NJE/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]
Subject: Re: Rehersal

Absolutely outstanding

----- Original Message -----
From: Maria Gordian
Sent: 01/20/2009 06:28 AM EST
To: Rob Rosiello; Martin Elling
Subject: Fw: Rehersal

We had a very good FDA rehearsal yesterday with several family members present...including Dr Richard and Jonathan. The team did an outstanding job on the study. preparing the client and executing the mock meeting. We are off to DC today for the actually FDA meeting tomorrow. Worth reading Dr Richard's comments below. Pasha and Laura are truly distinctive !!!

----- Forwarded by Maria Gordian/NYO/NorthAmerica/MCKINSEY on 01/20/2009 06:24 AM -----

"Sackler, Marianna" <Annie.Sackler@pharma.com>

01/19/2009 10:14 PM

To "Landau, Dr. Craig" <Dr.Craig.Landau@pharma.com>, "Weingarten, Brianne" <Brianne.Weingarten@pharma.com>, "Harris, Stephen" <Stephen.Harris@pharma.com>, "Giordano, Jennifer" <Jennifer.Giordano@pharma.com>, "Lee, Judy" <Judy.Lee@pharma.com>, "Santopolo, Anthony" <Anthony.Santopolo@pharma.com>, "Gasdia, Russell" <Russell.Gasdia@pharma.com>, "Colucci, Salvatore" <Salvatore.Colucci@pharma.com>
cc <Pasha_Sarraf@mckinsey.com>, <Laura_Nelson_Carney@mckinsey.com>, <maria_gordian@mckinsey.com>
Subject FW: Rehersal

Dear all,

I thought I would share this with you as per my father's request in advance of what promises to be an informative meeting on Wednesday.

Annie

From: Sackler, Dr Richard
Sent: Monday, January 19, 2009 3:58 PM
To: Sackler, Marianna
Subject: Rehersali

Marianna,

I am writing to tell you how impressed I was by the preparation for the FDA meeting. Both the method and process as well as the content was excellent and a major departure from efforts like this in the past.

Please share with the team my views and best wishes for a successful interchange with the FDA.

Warmest regards and best of luck to all…..

Richard Sackler, M.D.

Director, Purdue Pharma L.P.

Exhibit E

Message

From: Loren Griffith [CN=Loren Griffith/OU=BOS/OU=NorthAmerica/O=MCKINSEY]
Sent: 10/16/2008 7:02:42 PM
To: Maria Gordian [CN=Maria Gordian/OU=NYO/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]; Michelle Forrest [CN=Michelle Forrest/OU=NYO/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]; Rob Rosiello [CN=Rob Rosiello/OU=STA/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]; Elizabeth Laws [CN=Elizabeth Laws/OU=NJE/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]
CC: Jonathan Cain [CN=Jonathan Cain/OU=STA/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]
Subject: updated strategic options for Purdue on FDA-OxyContin-REMS
Attachments: 081016 Purdue FDA response options.zip

As per our discussion this morning, updated to include a new option: "band together" with other pharamcos doing C2 opioids to jointly strategize how to deal with the FDA. **Redact- Privileged**

Redact- Privileged

Loren

Loren Griffith | McKinsey & Company, Boston

081016 Purdue FDA response o...

mobile: 917 256-9085 | fax: 212 891-3020 | office: 617 753-2393

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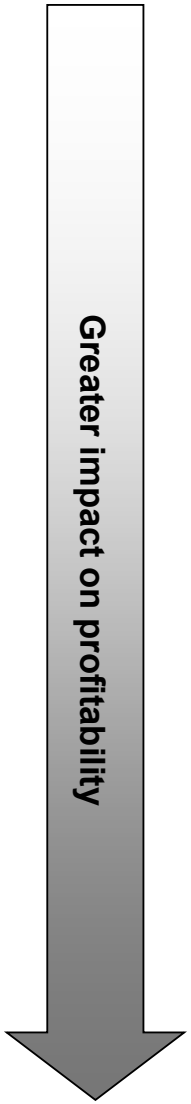
Outcomes for OxyContin range from business-as-usual to withdrawal



Business-as-Usual	• REMS approved for OxyContin, then OxyContin OTR approved and successful in holding market share against King's Remoxy (or Remoxy denied approval)	• Maintenance of current OxyContin revenues over 3-4 year timeframe
Intermediate outcome	• OxyContin restricted as result of voluntary or FDA-required action – Withdrawal of high-dose formulations – Sales/marketing restrictions – Tablet "tagging" – Distribution limited to certain doctors, pharmacies or geographies OR • King's Remoxy approved and takes some market share (perhaps due to delay or denial of OxyContin OTR)	• Significant but not devastating loss of OxyContin revenues over 1-2 year timeframe
Withdrawal from market	• FDA pulls OxyContin from market following – Rejection of REMS – Approval of Remoxy* (coupled with FDA perception that it is safer than OxyContin)	• Devastating loss of OxyContin revenues over 1-2 year timeframe

* King Pharma will likely also be required to submit a REMS for Remoxy

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Purdue's strategic options

NOT MUTUALLY EXCLUSIVE

	Approach	What you would have to believe to pursue this course
PLAY: Seek FDA approval for the REMS	• Develop a thorough REMS • Prepare to effectively implement and monitor the REMS	• Purdue can produce a high-quality REMS that the FDA will approve
DELAY: Delay any FDA actions	• Request additional time to respond • Raise legal claims alleging FDA impropriety, either immediately or after FDA finds Purdue's REMS inadequate and attempts to take action	• FDA willing to grant additional time • FDA has acted illegally in seeking a REMS or would be acting illegally in sanctioning Purdue if the REMS is found wanting
PRE-EMPT: Voluntarily curtail OxyContin	• Assess what FDA is most concerned about and what Purdue can do to address it (e.g. take high-dose versions off the market) and therefore persuade the FDA to withdraw its demand for a REMS	• FDA is concerned about particular aspects of OxyContin and can be persuaded not to take action if Purdue voluntarily addresses these aspects
BAND TOGETHER: Work with others facing potential FDA action	• Jointly develop FDA response strategy with other pharamacos marketing or developing Class 2 opioid analgesics (e.g. Cephalon's Fentora) – As appropriate, share abuse mitigation strategies – Formulate arguments to defend against strict treatment by the FDA	• These peers share similar interests in working with the FDA to achieve a balanced resolution, and joint action could be effective

1

Recommendations on actions to take immediately

REMS

- **Place Craig Landau in charge of overseeing REMS development**
  - Engage Pinney Associates to provide focused expertise on specified technical aspects

Scenario planning

- **Convene an "assessment" team** (leader TBD)
  - Headed by a strong thinker and project manager (and drawing on the best talent from finance, regulatory, R&D, etc.)
  - Responsibilities: assess probabilities of various FDA actions, cost out impact of various scenarios and provide strategic recommendations accordingly
- **Convene a "war games" team** (leader TBD)
  - Headed by an effective project manager
  - Responsibility: plan top team workshop in which several executives assume the roles of Purdue, the FDA, and King Pharma to explore each's values and likely actions in different scenarios

Strategic integration

- **Decide how to ensure Purdue pursues a coherent overall strategy and successfully pulls together REMS components**
  - CEO to lead with McKinsey
  - Other handpicked team members TBD

Exhibit F

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WORKING DRAFT

FDA Advisory Committee on Reformulated OxyContin: Question & Answer Book (for Reference)

Internal document

September 24, 2009

Contents

Hardest questions

A. Why not wait to approve the reformulation until you have in vivo data? (A "perfect" reformulation?)

B. Why haven't you done in vivo studies (we asked you to)?

C. Why not withdraw OxyContin (wouldn't this save lives)?

D. How will patterns of abuse shift among routes of administration? To other opioids? To illicit drugs?

E. What if abusers like reformulation better?

F. Isn't it embarrassing to Purdue to propose such a marginal improvement?

G. Nine years and this is it?

H. What happens when viscous solution of reformulated tablets are injected?

I. Won't increase tablet hardness introduce variability and lead to increase abusers overdosing on higher strength or multiple tablets?

J. Cat is out of the bag on "TR" – isn't this just a commercial ploy to increase OxyContin sales?

K. Why should we trust you?

L. Who at Purdue takes personal responsibility for all these deaths?

M. How does this reformulation affect the overall safety of OxyContin?

Why should we trust you?

- We acknowledge mistakes made in the past
- We have x, y and z measures in place that did not exist before
- At all levels, Purdue's focus is on maintaining the highest ethical standards and meeting the needs of patients

Who at Purdue takes personal responsibility for all these deaths?

- We all feel responsible

Exhibit G

Message

From: Jonathan Cain [Jonathan_Cain@mckinsey.com]
Sent: 10/16/2008 12:29:33 PM
To: Rob Rosiello [CN=Rob Rosiello/OU=STA/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]; Maria Gordian [CN=Maria Gordian/OU=NYO/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]; Michelle Forrest [CN=Michelle Forrest/OU=NYO/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]; Loren Griffith [CN=Loren Griffith/OU=BOS/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]
Subject: Purdue interview notes - Dennis O'Neill

Key takeaways
•Dennis is very negative about virtually all aspects of decision making quality and processes at Purdue
•He believes that the Board gets involved in too many decisions that it shouldn't, and that until it backs off, overall decision making at Purdue won't improve
•Purdue employees are good "servitors" who are fearful of speaking up in decision making processes because of "fear of failure"

Context
Dennis is an Organizational Development guy who works for David Long in HR. He has been with Purdue for 8 years.

Detail
•He believes that the Board gets involved in too many decisions that it shouldn't, and that until it backs off, overall decision making at Purdue won't improve
1)"The Board doesn't know whether they're a Board of Directors or owners"
2)The Board makes almost all the important decisions
3)John probably spends 80% of his time dealing with the Board
•Purdue employees are good "servitors" who are fearful of speaking up in decision making processes because of "fear of failure"
4)The brothers who started the company viewed all employees like the guys who "trim the hedges"--employees should do exactly what's asked of them and not say too much
5)This culture has taken root and now there's an unusually strong "fear of failure" (as per an employee survey)
•Purdue employees are angry that advancement opportunities have declined
6)"We used to get paid well; now we get screwed"
7)Recent shift to "broadbanding", which has reduced the number of rungs on the advancement ladder from 14 to 7, has meant that many promising up-and-comers have been unable to get promotions "until the guy in front of them dies"

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Exhibit H

Message

From: William Mallin [wmallin@optonline.net]
Sent: 10/21/2008 9:35:09 PM
To: rob_rosiello@mckinsey.com
Subject: Confidential

Rob:

Called you then found out both of you are in Barcelona. FYI I think JS may be at "tipping point" with Purdue Board. Getting some information that they may not be pleased with OXY and OTR plans and JS leadership of same. If you have any contact with him you may want to take the temperature ...lots of palpable concern over FDA threat to Oxy. Sending from home e mail as a heads up so no response necesssary, can catch up upon your return. Say hello to Martin.

Regards,

Bill

Exhibit I

Message

From: Jonathan Cain [Jonathan_Cain@mckinsey.com]
Sent: 10/22/2008 8:35:24 PM
To: Rob Rosiello [CN=Rob Rosiello/OU=STA/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]; Maria Gordian [CN=Maria Gordian/OU=NYO/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]; Michelle Forrest [CN=Michelle Forrest/OU=NYO/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]; Loren Griffith [CN=Loren Griffith/OU=BOS/OU=NorthAmerica/O=MCKINSEY@MCKINSEY]
Subject: Purdue interview notes - Phil Strassburger

Key takeaways
•Decision-making at Purdue is an "utter failure" if the results of the past 13 years are any measure
•There are two primary reasons for the inadequate decision-making in the US operation. The first is interference by the Board
•The second is an inadequate rewards system
•If Phil was CEO he would ensure he had decision-making autonomy and would reduce the level of interaction with the Board
•The two interdepartmental committees Phil is most involved with are well structured and have good processes

Context
Phil is VP, Intellectual Property Counsel reporting to Howard Udell. He has worked at Pfizer previously.

Detail
•Decision-making at Purdue is an "utter failure" if the results of the past 13 years are any measure
1)OxyContin was introduced 13 years ago and since then, despite thousands of man-hours and meetings, no new products have been approved and no new prescription drugs have been in-licensed
2)Europe and Asia have both managed to introduce new products and are relatively well diversified
3)The US remains a one-product company and it is a miracle it has retained exclusivity this long

•There are two primary reasons for the inadequate decision-making in the US operation. The first is interference by the Board
1)The European and Asian operations have the luxury of only meeting with the Board twice a year. Management at those meetings make formal, well-considered presentations, that are virtually always approved by the Board
2)In the US the Board is involved in all levels of decision-making on a weekly basis
3)Dr Richard in particular is highly involved. He is fascinated by negotiations but is "a terrible negotiator"
4)Phil can cite numerous deals that have been sabotaged by Dr Richard's meddling. As a result Purdue is viewed as a difficult company to deal with in the industry.
5)Decisions on deals are reversed on a monthly basis and there is no robust approach taken - it is whatever the Board's "flavor of the month" is

•The second reason is an inadequate rewards system
6)There is a culture of low risk taking and decision-avoidance at Purdue. As a manager, you get rewarded for pandering to the Board and not making mistakes.
7)Phil considers himself and Howard Udell as the lone managers prepared to voice a contrary view. He has seen his bonus go down as a result
8)The culture results in a lot of churn without much decision-making; where success is seen as neutral and anything else is a failure reflected in pay cuts. As a result, people defer decisions as much as possible

•If Phil was CEO he would ensure he had decision-making autonomy and would reduce the level of interaction with the Board
1)Currently there are weekly Board calls, with no prior agenda and no minutes. The entire Board is involved with various senior managers as required. John Stewart leads the calls, with support from others like Howard Udell when their area of expertise is discussed
2)Few decisions are made - when the occasional one is made a formal Board proposal is made and there will be a vote
3)There should be less meetings so that each one matters and there is more pressure/incentive to make decisions

•The two interdepartmental committees Phil is most involved with are well structured and have good processes
1)The Patent Review Committee reviews new inventions and decides whether to proceed with a filing. Each patent is a $100k investment

2)The Foreign Patent Filing Committee decides whether existing patents should be extended overseas. Each foreign filing is a $300k investment
3)Both committees circulate pre-read documentation a couple of weeks out, utilize standardized forms to review patents, and have a reporting mechanism after the meeting
4)Phil seldom goes to R&D Ops meetings any more - the meetings meander, and no one makes a decision on the matters he cares about. There's a culture of keeping all options open to avoid risk

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Exhibit J

Memorandum

To Olivier Hamoir
cc Kristine Lavik

From Maria Gordian
Date March 26, 2009

EY2009 Impact Summary

This memo summarizes my leadership contributions and impact during the past 18 months, focusing on the following areas:

- ¶ Developing, serving, and driving client impact at Purdue, Roche, Pfizer, GSK and New York University Medical Center
- ¶ Tackling the challenges of malaria
- ¶ Continuing to develop the Research and Development Interest Group
- ¶ Developing a new service model for PMP along with innovative knowledge to support broader client development
- ¶ Leading North American Diversity Recruiting.

DEVELOPING, SERVING AND DRIVING IMPACT FOR CLIENTS

Purdue: Turning things around

Client: World's leading opiate producer, privately owned by the Sackler family. Annual revenues of $5B.

CST and my role: In DCS and ED roles on studies, I worked with co-DCS Rob Rosiello and Martin Elling, Sanjeev Agarwal (Commercial), Tony Tramontin (R&D), and Rachel Zhang (R&D). I served as lead counselor to the CEO with Rob Rosiello, and lead counselor to head of R&D (Craig Landeau) and Operations (Bill Mallin), point of contact for the Board and Sackler family, and counselor to Richard Sackler.

Client impact: Over the last 12 months, we worked with Purdue to redefine their position in the market. We entered when they were facing a highly unstable and

challenging situation, with a $2B asset at risk of being pulled from the market. The acting CEO at the time, John Stewart, was struggling with waning board confidence, a recent non-approval letter from the FDA, and extremely low morale in the organization. Through a series of efforts, we secured the future of the crucial OxyContin franchise. The filing for the drug's reformulation is now positioned for approval, thanks in part to our re-design and re-execution of *in vivo* and *in vitro* testing—which got strongly positive responses from FDA—and our response to the agency's requirements for a risk mitigation strategy. These, along with several other victories, built the confidence of the Board and we believe played a key role in Stewart's appointment as CEO. Specific areas I focused on:

- ***Counsel the CEO***. Counseled Stewart with Rob Rosiello on his performance goals, a 100-day plan, how to work with the Board, where to upgrade his leadership team (e.g. head of R&D, head of Regulatory)
- ***Point of contact with Board and Sackler family***. Counseled Richard Sackler on alternative ways to make investments in the business, and provided framework for thinking about potential investments
- ***Fortify Purdue's foundation***. Maximized the value of the OxyContin franchise by directly supporting the submission of two pain assets. Providing a long-term vision that integrates the IP, R&D, and Commercial strategies
- ***Expand and diversify the portfolio.*** Identified Purdue's next generation of medicines for pain and attractive adjacencies
- ***Establish a high performance organization***. Restructured the executive committee, strengthened the operational committee structure and drove the operational "performance mindset" within the organization to enhance performance.

With client work extending through the 3rd quarter, and several additional proposals in progress, we continue to expand the depth and breadth of our relationships at Purdue. We look forward to deepening our relationships with the Sackler family and serving them on key business development issues, and to expanding our relationship with Stewart and other members of the senior management team.

Roche: A major investment in a purposeful journey

Client: With 2008 revenues of about $46 billion and a $100B market cap, Roche is one of the leading pharmaceutical companies in oncology and metabolic diseases.